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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,299	01/17/2002	Michael A. Zasloff	MZ 100	5008

7590 06/30/2004

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,299	ZASLOFF ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,25,31,32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,25,31,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Supplemental Response and Arguments/Remarks filed 03/22/04 and the Amendment and Applicant's Arguments/Remarks filed 02/13/04 is acknowledged.

Claims 1-16, 18, 25, 31, 32 and 34 are pending. Claims 1, 9, 10, 11, 18, 25, 31 and 32 are amended. Claims 1-16, 18, 25, 31, 32 and 34 are rejected.

This application contains claims 17, 19-24, 26-30, 33 and 35-40 drawn to an invention nonelected with traverse in the reply filed on 09/08/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1, line 3, recites "composition *comprising consisting essentially of*". Applicants have amended by adding the phrase "consisting essentially of" but have not deleted the term "comprising" from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-16, 18, 25, 31, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundstrom *et al.* (US Pat. No. 6,388,056 B1).

Sundstrom *et al.* teach compounds and methods for the prevention and treatment of microbial infection of a mammalian host through the administration of substrates for transglutaminases or antibodies against such substrates that inhibit the transglutaminase-mediated interaction with the mammalian host. These compounds and methods may be used in the identification, prevention or treatment of microbial infection of mammalian hosts, such as, for example, immunocompromised or immunosupressed humans. (see Abstract and col. 1, lines 1-15). The polypeptides used in the invention act as substrates for mammalian transglutaminases and include amino acids of *isoleucine*, serine and glutamine, whereby the amino acid residues are preferred to be in the L isomeric form, however the D isomeric form may also be used (col. 9, line 5 – col. 10, line 11).

Sundstrom teach that during initial infection, the interaction of a microorganism with its mammalian host can include attachment or adhesion to the host cell surface, invasion of host cells, and elaboration of toxins. In certain

instances, this interaction can be nonspecific. In others, such microbial interaction involves the specific binding of the microorganism to a particular receptor or receptor complex expressed on the host cell surface (col. 1, lines 20-32).

According to Sundstrom *et al.,* the antibody is capable of inhibiting the interaction of a microorganism with a mammalian cell. The mammalian cell is a human cell, preferably an epithelial cell, more preferably a mucosal epithelial cell and most preferably a buccal epithelial cell (col. 4, lines 20-50).

At column 8, lines 34-52, Sundstrom *et al.* teach that in a preferred embodiment, a substrate for mammalian transglutaminases can inhibit the binding of one or more mammalian transglutaminases to purified Hwp1 protein or a polypeptide comprising the amino acid sequence of Fig. 1, wherein said polypeptide is itself capable of acting as a substrate for mammalian transglutaminases. In addition, microbial interaction with a mammalian host can include attachment or adhesion to the host cell surface, invasion of host cells, and elaboration of toxins, for example. The involvement of pathogenic mechanisms or virulence factors of the microorganisms can result in beneficial effects to the mammalian host.

In Example 7, cols. 19 and 20, Sundstrom *et al.* teach a pharmaceutical composition containing polypeptide substrates for mammalian transglutaminases in powder form, along with pharmaceutical carriers, which could also be prepared as a liquid preparation suitable for injection, for the purpose of inhibiting transglutaminase-mediated microbial interaction with a mammalian host. The

peptides may be delivered by any convenient means that will result in the delivery to the subject of an effective amount to inhibit transglutaminase-mediated microbial interaction with a mammalian host. The amount administered will depend on the activity of the particular compound administered, which may readily be determined by one skilled in the art.

It is the position of the Examiner that the prior art teaches the generic concept of the use of isoleucine to inhibit microbial infection and interaction with the mammalian host, since isoleucine is within the group of polypeptides disclosed at columns 10 and 16. One of ordinary skill would recognize that since isoleucine is taught to inhibit microbial interaction, it also teaches the prevention of the adherence of microbes, as desired by the applicant. Hence, no significant distinction is observed between the prior art and the instant invention.

With regards to the instantly claimed amounts and ranges of isoleucine employed, it is deemed obvious to one of ordinary skill in the art that suitable amounts and ranges could be determined through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters.

Response to Arguments

Applicant's arguments filed 2/13/04 & 3/22/04 have been fully considered but they are not persuasive.

Firstly, the Applicant argued regarding Sundstrom et al. (US 6,388,056 B1) stating, "Sundstrom's patent is directed to a long chain polypeptide containing isoleucine among a large number of other amino acids, all of which are set forth in a set fixed sequence in the polypeptide chain. There is no disclosure in Sundstrom of isoleucine itself.

Secondly, Sundstrom's polypeptide functions by a different mechanism, namely the prevention and treatment of microbial infection of a mammalian host through the administration of substrates for transglutaminases or antibodies against such substrates that inhibit the transglutaminase-mediated interaction of the microorganism with the mammalian host. There is no teaching of isoleucine itself or the teaching that isoleucine can function to block microbial adherence to the surfaces of eukaryotic cells. The only teaching by Sundstrom is respect to the adherence of microbes to host cell surfaces, but not even a teaching that the polypeptide can block such adherence by microbes. Isoleucine is not taught to inhibit microbial interaction as contended by the Examiner since Sundstrom contains no disclosure of isoleucine itself or the present discovery that isoleucine blocks microbial adherence to cell surfaces."

These arguments have been fully considered, but were not found to be persuasive. The instant claims are given their broadest interpretation consistent with the teachings of the specification. Applicant's specification and claims do not exclude the polypeptides or the amino acids defined in Sundstrom *et al.* When Applicant alleges that the term "consisting essentially of" excludes the presence of additional active ingredients, the burden is shifted to Applicant to show that the addition of polypeptides or amino acids is detrimental to the formulation.

The Applicant's argument that Sundstrom et al. utilizes a different mechanism from that instantly claimed is not persuasive since the particular mechanism is not relevant for the generic claims because Sundstrom et al. teach the use of isoleucine and teach a polypeptide composition comprising isoleucine. Applicant's claims merely require presence of isoleucine in a microbial blocking quantity. Additionally, Examiner notes that suggestions were made in the personal interview to further limit the term "microbial" in instant claim 1, since the term is very broad in that it includes various bacteria, viruses, yeast, fungi, etc. The term has not been further defined or limited, nor has any scientific data or clear evidence been presented showing that the claimed compound of Formula (I) treats all microbial organisms. The prior art teaches the same ingredients (i.e., isoleucine) for the same field of endeavor and to solve a similar problem as that desired by Applicants. Hence, the instant invention remains obvious and unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns HNS
June 14, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600